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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,422	04/04/2006	Pyare L. Seth	Q88273	4203

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
06/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,422	SETH, PYARE L.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *22 Jan 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed March 12, 2007. All previous rejection have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Objections

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim recites the limitation that Pirfenidone comprises 1-25 % by weight of the composition. The independent claim 1 recites Pirfenidone comprises about 10% to about 25% of the compositions. Therefore claim 9 fails to further limit claim 1.

Claim Rejections - 35 USC § 102 – Anticipation (New Rejections)

1) Claims 1-2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheiwe et al. (US 6,492,395).

Scheiwe et al. disclose pharmaceutically acceptable topical formulations comprising pirfenidone. The compositions are in the form of emulsions, creams, gels, ointments, microemulsions, liquid emulsions and lotions. The excipient permits the

dissolution or dispersion of a sufficient amount of pirfenidone, i.e., it is a solvent. Pirfenidone comprises from about 0.5% to about 9% (col. 2, lines 31-35), which is "about" 10%, by weight of the compositions. Antioxidants include sodium metabisulfite and alpha-tocopherol and are included in a concentration ranging from 0.02% to 2 wt. %. Plasticizers include alkyl glycols and polyalkylene glycols and are included in the compositions. Gelling agents include hydroxypropyl cellulose. Water comprises 20 to 80 wt. % and ethanol comprises 0 to 20 wt % of the compositions (col. 2, lines 38-63 and col. 3, lines 33-52). Methyl and propyl paraben may also be included and comprise 0 to 0.5% of the compositions (col. 3, lines 14-16 and col. 3, lines 33-52). The reference anticipates the instant claims insofar as it discloses a liquid composition comprising a pyridone derivative in a concentration of about 10% in a solvent.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 1-2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margolin (WO 94/26249).

Margolin discloses compositions comprising N-substituted 2-(1H) pyridones in topically administered dosage forms in an amount of from about 1% to about 20% (claim 15). The pharmaceutical compositions may be in the form of creams, ointments, hydrophilic ointments, inhalable fluids, eye drops, syrups and suppositories (page 22, lines 31-34). The preferred preparations include creams, infections and ointments (page 20). The ointments of the reference comprise 5% to 10% pirfenidone (Test Example 2).

Although the solvent was not disclosed, because the compositions may be formulated into injection, a solvent must be present. The reference differs from the instant claims insofar as it does not disclose an example of a pharmaceutical liquid such as an injection comprising a pyridone derivative and a solvent.

The reference is not anticipatory insofar as one must "pick and choose" from different lists of dosage forms and the concentration of pyridone derivative in the dosage form. That being said, it would have been obvious in a self-evident manner to have selected an injection from one list and pirfenidone at a concentration from 10 to 20%, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners.

2) Claims 3-4 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiwe et al. (US 6,492,395) in view of Iyer et al. (US 2004/0033257).

The primary reference, Scheiwe et al., is discussed above in the anticipation section subsection 1. The reference differs from the instant claims insofar as it does not disclose the compositions comprise diethylene glycol monoethyl ether as a solvent.

Iyer et al. disclose oral compositions comprising solvents useful for poorly soluble pharmaceuticals. The solvents include diethylene glycol monoethyl ether, which acts as a powerful solubilizer for several poorly soluble drugs. It is soluble in water and ethanol

(paragraph 0024). It also can act as a co-surfactant. The diethylene glycol monoethyl ether used was purified diethylene glycol monoethyl ether. The reference differs from the instant claims insofar as it does not disclose pyridone derivatives as the drugs that are solubilized.

It would have been obvious to one of ordinary skill in the art to have used diethylene glycol monoethyl ether as a solvent or co-solvent in place of water or in combination with water in the compositions of the primary reference motivated by the desire use a powerful solubilizer to dissolve a poorly soluble drug, as taught by the secondary reference.

3) Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margolin (WO 94/26249) in view of Iyer et al. (US 2004/0033257).

The primary reference is discussed above in subsection 1. The reference differs from the instant claims insofar as it does not teach the compositions comprise diethylene glycol monoethyl ether as a solvent.

Iyer et al. discloses oral compositions comprising solvents useful for poorly soluble pharmaceuticals. The solvents include diethylene glycol monoethyl ether, which acts as a powerful solubilizer for several poorly soluble drugs. It is soluble in water and ethanol (paragraph 0024). It also can act as a co-surfactant. The reference differs from the instant claims insofar as it does not disclose pyridone derivatives as the drugs that are solubilized.

It would have been obvious to one of ordinary skill in the art to have used a solvent such as diethylene glycol monoethyl ether in the compositions of the primary reference motivated by the desire use a powerful solubilizer to dissolve a poorly soluble drug, as taught by the secondary reference.

Claims 1-11 are rejected.

Claim 9 is objected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614